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09/762,134	01/31/2001	Takuro Tamura	07898-067001	7717

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,134

Applicant(s)

TAMURA ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 4-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 15 March 2004 in which claims 4-7 were amended and claim 8 was added. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 15 December 2003, not reiterated below, are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed and are discussed below as they apply to the new grounds for rejection. New grounds for rejection, necessitated by the amendments are discussed.

Claims 1-3 are withdrawn.

Claims 4-8 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 4, 7 and 8 are indefinite in Claim 4, lines 7 and 9 for the recitation "said on-chip-element" because the recitation lacks proper antecedent basis in the claim. It is suggested that Claim 4 be amended to provide proper antecedent basis.

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b. Claims 4, 7 and 8 are indefinite in Claim 4, line 9 for the recitation “corresponding location” because “corresponding” is a non-specific relational term therefore, it is unclear how corresponding modifies the “location”. It is suggested that Claim 4 be amended to clarify e.g. --
- wherein the information includes type and location of said non-index spot--- .

c. Claims 4, 7 and 8 are indefinite in Claim 4, line 11 for the recitation “automatically identifying” because “automatically” can be a mental or mechanical step. However, it is unclear within the context of the claim how “automatically” modifies the identifying.

d. Claims 5 and 6 are indefinite in Claim 5, lines 6 and 8 for the recitation “said on-chip-element” because the recitation lacks proper antecedent basis in the claim. It is suggested that Claim 5 be amended to provide proper antecedent basis.

e. Claims 5 and 6 are indefinite in Claim 5, line 8 for the recitation “corresponding location” because “corresponding” is a non-specific relational term therefore, it is unclear how corresponding modifies the “location”. It is suggested that Claim 5 be amended to clarify e.g. --
- wherein the information includes type and location of said non-index spot--- .

f. Claims 5 and 6 are indefinite in Claim 5, line 11 for the recitation “automatically identifying” because “automatically” can be a mental or mechanical step. However, it is unclear within the context of the claim how “automatically” modifies the identifying.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent

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or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 4 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Wolber (U.S. Patent No. 6,284,465, filed 15 April 1999).

Regarding Claim 4, Wolber discloses a method of indexing a microarray comprising selecting spots as indexing spot (i.e. non-probe regions/probe features, Column 8, lines 31-42), spotting target onto non-index spots (probe containing/probe features), indexing the microarray by providing detectable colorant (i.e. label, Column 13-Column 14, line 24) onto the index spot based on type and location of the non-index spot and detecting the colorant to thereby identify the microarray (i.e. the components of the microarray)(Column 15, lines 23-49 and Column 20, lines 16-27).

Regarding Claim 5, Wolber discloses a method of indexing a microarray comprising selecting spots as indexing spot (i.e. non-probe regions/probe features, Column 8, lines 31-42), spotting target onto non-index spots (probe containing/probe features), indexing the microarray by providing detectable colorant (i.e. label, Column 13-Column 14, line 24) onto the index spot based on type and location of the non-index spot and reproducing the index information (i.e. compares actual locations with data collected, Column 20, lines 16-27) by detecting the colorant to thereby identify the microarray (Column 15, lines 23-49).

6. Claims 4-6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Noblett (U.S. Patent No. 6,471,916, filed 9 November 1999).

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Regarding Claim 4, Noblett disclose a method of indexing a microarray comprising selecting spots as indexing spot (i.e. dilution spots having fluorophore material, Abstract and Fig. 2 & 4), spotting target onto non-index spots, indexing the microarray by providing detectable colorant (i.e. label, Column 3, lines 10-29) onto the index spot based on type and location of the non-index spot and detecting the colorant to thereby identify the microarray (Column 4, line 51-Column 5, line6 and lines 44-65).

Regarding Claim 5, Noblett discloses a method of indexing a microarray comprising selecting spots as indexing spot (i.e. dilution spots having fluorophore material, Abstract and Fig. 2 & 4), spotting target onto non-index spots, indexing the microarray by providing detectable colorant (i.e. label, Column 3, lines 10-29) onto the index spot based on type and location of the non-index spot and detecting the colorant to thereby identify the microarray (Column 4, line 51-Column 5, line 6 and lines 44-65) reproducing the index information by detecting the colorant to thereby identify the microarray(i.e. positional feedback and adjustments, Column 5, lines 25-43).

Regarding Claim 6, Noblett discloses the method of Claim 6 further comprising a two-dimensional matrix of index spots designed as parity spots provided with colorant (i.e. dye-containing dilution spots for equating signals, Column 5, lines 44-65) and the parity spots are checked for errors i.e. at each detection, the fluorescence is measured, analyzed and concentration computed, Column 5, lines 54-65).

Regarding Claim 8, Noblett discloses the method of Claim 4 wherein index spots are parity spots (i.e. dye-containing dilution spots for equating signals, Column 5, lines 44-65) and further comprising reproducing the index information by detecting the colorant to thereby identify the microarray (i.e. positional feedback and adjustments, Column 5, lines 25-43).

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Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al (U.S. Patent No. 5,812,272, filed 30 January 1997) in view of Noblett (U.S. Patent No. 6,362,004, filed 9 November 1999).

Regarding Claims 4,5 and 7, The claims are drawn to a method of indexing a microarray chip by indexing spots on the array based on information of type and location of spot and detecting spots to identify the microarray. The method includes the steps of selecting indexing spots and spotting biological elements onto non-indexing spots.

King teaches indexing microarray wherein the indexing includes information regarding type and location of spots for identifying the microarray, reproducing the index information and constructing a database for recoding indexing information (Column 11, lines 32-56). King does not provide specific steps of selecting the index spots and spotting biological elements onto non-indexing spots. However, the selection and spotting was well known in the art as taught by Noblett who teaches index spots, non-index spots and spotting thereof to provide location information regarding the microarray (i.e. Noblett uses fiducial spots for maintaining position information, Column 5, lines 20-48; Column 6, lines 41-Column 7, line 20). Noblett further teaches the index spots are useful for focusing and adjusting sensitivity of the detector (Column 7, lines 31-52).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known index spot selection and spotting taught by

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Noblett to the microarray indexing of King for the expected benefit of maintaining position information of the microarray and further for facilitating focusing and adjusting sensitivity of the detector as taught by Noblett (Column 7, lines 31-52).

9. Claims 4, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balaban et al (U.S. Patent No. 6,188,783, filed 24 July 1998) in view of Noblett (U.S. Patent No. 6,362,004, filed 9 November 1999).

Regarding Claim 4, Balaban et al disclose a method for indexing a microarray chip comprising a plurality of spots arranged in a predetermined positional relationship, the method comprising the step of using some of the plurality of spots for maintaining the index information (i.e. interrelating probes on a chip providing a relational database, Column 2, lines 28-49).

Regarding Claim 5, Balaban et al disclose a method for indexing a microarray chip comprising a plurality of spots arranged in a predetermined positional relationship, the method comprising the step of using some of the plurality of spots for maintaining the index information (i.e. interrelating probes on a chip providing a relational database, Column 2, lines 28-49) wherein the index information is reproduced by detecting the presence of a detective colorant on the index spots i.e. labeled probes (Column 4, lines 19-51).

Regarding Claim 6, Balaban et al disclose the method of Claim 5 wherein information detected is realigned into a two-dimensional matrix upon reproducing the information (i.e. scanned) and part of the information is used as parity information (i.e. intensity as a function of position, Column 4, lines 19-51).

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Regarding Claim 7, Balaban et al disclose the method of Claim 4 comprising constructing a database for storing an element information record (e.g. sequence items), a microarray chip master record (chip design and/or genomic items) and an on-chip-element information record (e.g. chip design objectives and/or tiling) (Column 3, lines 30-51 and Column 6, lines 7-28), recording information of an element on the information record, recording information of the microarray chip, recording information on the on-chip information regarding location, element index and spot measurement (Column 4, lines 41-64) linking the microarray chip with the microarray chip record and linking the on-chip element with the element information e.g. relating the sequences to the genomic design and tiling (Column 7, lines 30-67 and Column 9, lines 31-65).

Balaban et al do not specifically teach steps of selecting the index spots and spotting biological elements onto non-indexing spots. However, the selection and spotting was well known in the art as taught by Noblett who teaches index spots, non-index spots and spotting thereof to provide location information regarding the microarray (i.e. Noblett uses fiducial spots for maintaining position information, Column 5, lines 20-48; Column 6, lines 41-Column 7, line 20). Noblett further teaches the index spots are useful for focusing and adjusting sensitivity of the detector (Column 7, lines 31-52).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known index spot selection and spotting taught by Noblett to the microarray indexing of Balaban et al for the expected benefit of maintaining position information of the microarray and further for facilitating focusing and adjusting sensitivity of the detector as taught by Noblett (Column 7, lines 31-52).

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10. Claims 4, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shams (U.S. Patent No. 6,349,144, filed 7 February 1998) in view of Noblett (U.S. Patent No. 6,362,004, filed 9 November 1999).

Regarding Claim 4, Shams discloses a method for indexing a microarray chip comprising a plurality of spots arranged in a predetermined positional relationship, the method comprising the step of using some of the plurality of spots for maintaining the index information (Abstract).

Regarding Claim 5, Shams discloses a method for indexing a microarray chip comprising a plurality of spots arranged in a predetermined positional relationship, the method comprising the step of using some of the plurality of spots for maintaining the index information wherein the index information is reproduced by detecting the presence of a detective colorant on the index spots i.e. labeled probes (Column 11, lines 16-40).

Regarding Claim 6, Shams discloses the method of Claim 5 wherein information detected is realigned into a two-dimensional matrix upon reproducing the information (Column 10, lines 44-65 and Fig. 8) and part of the information is used as parity information (i.e. extract background, Column 11, line 16-Column 12, line 3).

Regarding Claim 7, Shams discloses the method of Claim 4 comprising constructing a database for storing an element information record (e.g. set of DNA spot images), a microarray chip master record (image frame) and an on-chip-element information record (e.g. grid including position information) (Column 5, lines 48-62), recording information of an element on the information record, recording information of the microarray chip, recording information on the on-chip information regarding location, element index and spot measurement (Column 5, lines 48-62 and Fig. 3) linking the microarray chip with the microarray chip record and linking the on-chip element with the element information e.g. relating the sequences to the genomic design and tiling (Column 12, line 58-Column 13, line 34).

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Shams does not specifically teach steps of selecting the index spots and spotting biological elements onto non-indexing spots. However, the selection and spotting was well known in the art as taught by Noblett who teaches index spots, non-index spots and spotting thereof to provide location information regarding the microarray (i.e. Noblett uses fiducial spots for maintaining position information, Column 5, lines 20-48; Column 6, lines 41-Column 7, line 20). Noblett further teaches the index spots are useful for focusing and adjusting sensitivity of the detector (Column 7, lines 31-52).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the well known index spot selection and spotting taught by Noblett to the microarray indexing of Shams for the expected benefit of maintaining position information of the microarray and further for facilitating focusing and adjusting sensitivity of the detector as taught by Noblett (Column 7, lines 31-52).

11. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al (U.S. Patent No. 5,812,272, filed 30 January 1997) or Balaban et al (U.S. Patent No. 6,188,783, filed 24 July 1998) or Shams (U.S. Patent No. 6,349,144, filed 7 February 1998) Noblett(A): (U.S. Patent No. 6,362,004, filed 9 November 1999) as applied to Claims 4 and 5 above and further in view of Noblett(B): (U.S. Patent No. 6,471,916, filed 9 November 1999).

Claims 4 and 5 have been discussed above regarding methods of microarray indexing.

The methods of Balaban, Shams and King differ from the instant claims in that Balaban, Shams and King do not specifically teach index spots designated as parity spot.

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Regarding Claims 6 and 8, Noblett(B) teaches a similar method discloses a method of indexing a microarray , comprising selecting spots as indexing spot (i.e. dilution spots having fluorophore material, Abstract and Fig. 2 & 4), spotting target onto non-index spots, indexing the microarray by providing detectable colorant (i.e. label, Column 3, lines 10-29) onto the index spot based on type and location of the non-index spot and detecting the colorant to thereby identify the microarray (Column 4, line 51-Column 5, line 6 and lines 44-65) reproducing the index information by detecting the colorant to thereby identify the microarray(i.e. positional feedback and adjustments, Column 5, lines 25-43) wherein information detected is realigned into a two-dimensional matrix upon reproducing the information (Column 7, lines 21-Column 8, line 4) and part of the information is used as parity information i.e. to equally focus the probe spots (Column 7, lines 31-43). Noblett specially teach the parity spots provide a "concentration-to-brightness curve" whereby concentration of a sample is analyzed and sensitivity of the detector is adjusted (Column 5, lines 33-65).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the parity spots of Noblett to the indexing methods of Balaban, Shams or King for the expected benefit of facilitating sample analysis and sensitivity of the detector as taught by Noblett (Column 5, lines 33-65).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

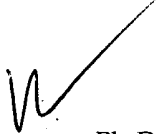
Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
May 21, 2004